Impact of sociodemographic characteristics and drug-related side effects on quality of life of patients with hepatocellular carcinoma receiving sorafenib treatment in Iraqi hospitals

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Abstract

Background: Sorafenib is an oral multikinase inhibitor which has been given approval by the United States Food and Drug Administration for the treatment of patients diagnosed with hepatocellular carcinoma and advanced renal cell carcinoma . However, measuring quality of life and patient-reported symptoms may provide further information for evaluating and comparing treatment efficacy and toxicity profiles during cancer treatment. Despite the critical importance of patients' quality of life while receiving anticancer treatment, neither Iraqi patients undergoing anti-cancer medications in general nor those receiving Sorafenib in particular had any published data evaluating this important parameter.

Objectives: The study aimed to assess the quality of life of Sorafenib-treated Iraqi patients diagnosed with hepatocellular carcinoma.

Methods: A prospective, cross-sectional study was performed at the oncology clinic of (Oncology Teaching Hospital, Al-Amal Hospital and Al -Imamein Al- Kadhimein Medical City in Baghdad, Iraq) during the period from November 2021 to July 2022. Patients were enrolled in current study by using a convenient sampling method. Assessment of quality of life was performed using a questionnaire from the "European Organization for Research and Treatment of Cancer". Statistical analyses were performed using statistical package for Social Sciences. Student's *t*-test and ANOVA test were used to compare categorical data. P value of <0.05 was considered statistically significant.

Results: The present study included 52 patients in total. Of the latter, 90.4% experienced fatigue, making it the most frequent adverse event, followed by anorexia, anemia, nausea, diarrhea and vomiting (71.2%, 67.3%, 65.4%, 59.6%, 26.9%, respectively). In spite of that, some participants had a good quality of life while others did not.

Conclusion: Patients with hepatocellular carcinoma on sorafenib treatment have variable quality of the life. The latter is significantly affected by patients' sociodemographic characteristics and treatment-related adverse events.

Keywords: Hepatocellular carcinoma, Multikinase inhibitor, Quality of life, Sociodemographic, Sorafenib.

Introduction:

Liver cancer is ranked sixth in incidence among all types of malignancy worldwide (1). In addition, the most common type of primary liver cancer is hepatocellular carcinoma (HCC). and the third greatest cause of mortality globally (2). Also, men are 2-3 times more likely than women to be affected (3). According to epidemiological studies, both environmental and ethnic factors are key determinants of HCC (3). The possible mechanisms

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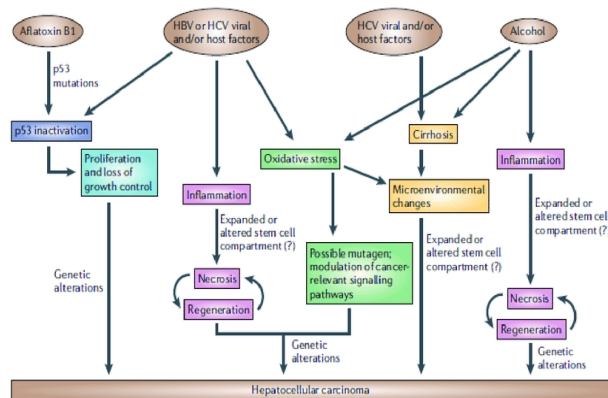
Impact of sociodemographic characteristics and drug-related side effects
on quality of life of patients with hepatocellular carcinoma receiving sorafenib
treatment in Iraqi hospitals   *Tuqa H. Qasim*

Figure (1) Mechanisms of hepatocarcinogenesis (4).

However, hepatic tumors are diagnosed definitively involved in the pathogenesis of HCC are described via percutaneous biopsy (3) and alpha fetoprotein (α-FP) in serum (5). In addition, ultrasonography, magnetic resonance imaging, computed tomography, computed tomographic portogram, arteriographically-enhanced CT and hepatic arteriography are some of the imaging methods used to determine the size and location of tumors (3). On the other hand, the overall goal of treatment is to slow the progression of the disease and reduce mortality (6). Hepatocellular carcinoma had no standard treatment before 2007 and clinicians often utilized cytotoxic chemotherapy, but its effectiveness was debated due to a lack of high-quality evidence and concerns about toxicity in cirrhotic patients. So that, Sorafenib was the first systemic treatment to show a survival benefit in a randomized controlled trial in 2007 (7). Its mechanism of action is demonstrated in Figure (2).
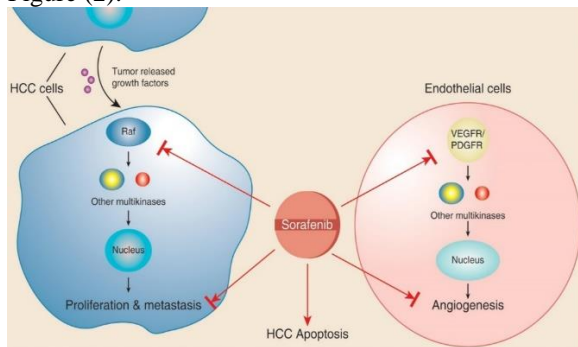

Figure (2) Mechanism of action of sorafenib (8).

Regardless of the fact that sorafenib is an effective treatment for HCC, it is accompanied by several side effects (9). These include weight loss, fatigue, anorexia, diarrhea or constipation, abdominal pain, nausea, vomiting, rash-desquamation, alopecia and hand-foot-skin reaction (10). One or more aspects of quality of life (QoL) (11) can be disrupted as a result of cancer and associated treatment regimens. Also, QoL is becoming more widely utilized in daily clinical practice to measure the efficacy of a treatment, and it may soon become a parameter that aids patients and physicians in making therapeutic decisions (12). Patients, rather than monitoring lipoprotein levels, blood pressure, or an electrocardiogram, make healthcare decisions based on QoL which evaluates the effects on outcomes that are important for them (11). As a result, there is a consequent need to meet the needs of cancer patients in order to live a healthy life (13).

The ideal QoL measurement tool for regular clinical practice must be brief, easy to understand for patients, address relevant QoL concerns, and be dependable and change-responsive (14). One such tool is the "European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30)" (15).

In spite of the importance of patients' QoL while undergoing anti-cancer treatment, it had not been evaluated in the literature for Iraqi HCC patients on anti-cancer medications in general, or those undergoing Sorafenib, in particular. Therefore, the aim of current research was to assess the side effects profile of sorafenib as well as quality of life of Iraqi patients with HCC who were undergoing Sorafenib treatment in Iraqi hospitals.

Methods

This is a prospective cross-sectional study conducted at the Oncology Teaching Hospital, Al-Amal Hospital and Al -Imamein Al- Kadhimein Medical City in Baghdad, from November 2021 to July 2022. It was planned to recruit 50 patients, or more, who were taking sorafenib for their HCC. A convenient sampling method was adopted to enroll the participants in current study and they were asked to participate voluntarily after an adequate explanation about the aim and method of study. All participants were assured of anonymity and confidentiality of the information. Verbal consent was obtained from each participant. Their age should be ≥18 years and they should be able to provide an informed consent. Patients with other types of cancer and/or respiratory, renal, diabetes mellitus, hypertension, cerebrovascular, cardiovascular disease as well as pregnant and/ or nursing mothers were excluded from the study. Data were collected using a validated questionnaire through interviews performed by the researchers with the participants, and included: Sociodemographic characteristics (gender, age, education, residence, and employment), adverse events associated with sorafenib treatment (by measuring liver function test, renal function test, and white blood cell count) and assessment of QoL of patients. The latter was done using the European Organization for Research and Treatment of Cancer (EORTC) QoL questionnaire QLQ-C30(15) which had been developed as a quantitative measure of health-related QoL for use in clinical trials of cancer patients. The 30 items of the EORTC QLQ-C30 cover 15 domains (16). Scoring (Table 2.1) and the interpretation of scores for the EORTC QLQ-C30 were performed according guidelines provided (17,18). Microsoft Excel 2019 and the "Statistical Package for the Social Sciences (SPSS, Version 20)" were used for data entry and analysis. Quantitative data were presented as (mean, standard deviation and range). The ANOVA and *t*-tests were used to detect the differences between means. The significance level was set at P≤0.05.

Impact of sociodemographic characteristics and drug-related side effects on quality of life of patients with hepatocellular carcinoma receiving sorafenib treatment in Iraqi hospitals

Tuqa H. Qasim

Table 2.1: Scoring the QLQ-C30 version 3.0 (16).

Scale/ item	Number of items	Items range value	Items number
Global health status/QoL	2	6	29, 30
Functional scales			
Physical functioning	5	3	1 to 5
Role functioning	2	3	6, 7
Emotional functioning	4	3	21 to 24
Cognitive functioning	2	3	20, 25
Social functioning	2	3	26, 27
Symptom scales/items			
Fatigue	3	3	10, 12, 18
Nausea and vomiting	2	3	14, 15
Pain	2	3	9, 19
Dyspnea	1	3	8
Insomnia	1	3	11
Appetite loss	1	3	13
Constipation	1	3	16
Diarrhea	1	3	17
Financial difficulties	1	3	28

Results

Demographic data of participants: A total of 52 patients were enrolled in current study, 34 were males (65.4%) and 18 were females (34.6%). Patients aged 51-60 years constituted the largest age group (34.6%). In addition, 67.3% of the patients were living in urban areas, 73.1% of them were unemployed and 40.4% had college or higher education (Table 3.1).

Table 3.1: Demographic characteristics of participants

Demographic characteristic		No.	%
Gender	Male	34	65.4%
	Female	18	34.6%
Age group/yr	≤40	6	11.5%
	41-50	15	28.8%
	51-60	18	34.6%
	61-70	11	21.2%
	>70	2	3.8%
Education	Primary school	20	38.5%
	Secondary school	11	21.2%
	College or higher	21	40.4%
Residency	Urban	35	67.3%
	Rural	17	32.7%
Employment	Yes	14	26.9%
	No	38	73.1%

Quality of Life of participants on Sorafenib treatment: Regarding the functional scales of EORTC QLQ-C30, emotional scale and social scale were the most affected, with a lower mean than other scales. Among symptoms scale, fatigue scale and appetite loss scale were the most affected scales, with a higher mean than other scales (Table 3.2).

Table 3.2: The mean (SD) scores of EORTC QLQ-C30 domains for current study participants

EORTC QLQ-C30 domain	Mean	SD	Minimum	Maximum
Global health status/QoL	42.79	16.25	0.00	83.33
Functional Scale				
Physical scale	60.51	15.78	26.67	93.33
Role scale	63.14	20.44	16.67	100.00
Emotional scale	57.69	20.80	8.33	100.00
Cognitive scale	72.76	20.88	16.67	100.00
Social scale	54.17	22.60	0.00	100.00
Symptom Scale				
Dyspnea scale	22.44	23.54	0.00	66.67
Insomnia scale	33.33	28.77	0.00	100.00
Appetite loss scale	41.02	21.51	0.00	100.00
Nausea scale	25.64	21.76	0.00	66.67
Constipation scale	20.51	24.83	0.00	66.67
Diarrhea scale	29.49	28.51	0.00	100.00
Fatigue scale	56.62	17.08	22.22	100.00
Pain scale	37.50	23.54	0.00	100.00
Financial scale	58.33	23.68	0.00	100.00
QLQ-C30 summary score	46.19	5.91	35.28	57.92

SD: Standard Deviation.

Association between participants' demographic data and their quality of Life

The age of the patients was significantly associated with physical scale, role scale, fatigue scale, and pain scale (P<0.05). In addition, there was a significant difference between males and females concerning the emotional scale (P<0.05). Also, data from the current study showed that there was no significant difference between rural and urban residence on the different studied parameters (P>0.05). Moreover, the current study showed that there was a significant difference in the dyspnea scale between employed and unemployed participants (P<0.05). Furthermore, results from the current study showed that there was no significant difference regarding educational status in relation to the different study parameters (P>0.05). Association between participants' quality of life and their experience of adverse drug effects The QLQ-C30 mean scores were significantly higher among patients with weight loss (Table 3.8).

Table 3.3: Association between participants' quality of life and their experience of adverse drug effects

Adverse effect		QLQ-C30 score		P value
		Mean	SD	
Fatigue	Negative	45.89	6.39	0.905
	Positive	46.23	5.93	
Anorexia	Negative	45.00	5.68	0.359
	Positive	46.68	6.01	
Nausea	Negative	44.14	6.86	0.099
	Positive	47.28	5.13	
Vomiting	Negative	46.10	6.51	0.848
	Positive	46.46	4.07	
Diarrhea	Negative	44.56	5.37	0.102
	Positive	47.30	6.09	
Constipation	Negative	47.25	5.71	0.089
	Positive	44.35	5.97	

Impact of sociodemographic characteristics and drug-related side effects   *Tuqa H. Qasim*
on quality of life of patients with hepatocellular carcinoma receiving sorafenib
treatment in Iraqi hospitals

Abdominal pain	Negative	45.84	6.57	0.645
	Positive	46.61	5.15	
Hand foot skin reaction	Negative	45.73	6.45	0.421
	Positive	47.15	4.65	
Weight loss	Negative	44.64	5.73	0.003
	Positive	49.69	4.84	
Anemia	Negative	48.21	6.65	0.087
	Positive	45.21	5.35	
Low WBC count	Negative	46.37	5.89	0.836
	Positive	46.03	6.05	
Liver function	Abnormal	45.79	5.78	0.571
	Normal	46.74	6.17	
Renal function	Abnormal	45.25	5.97	0.294
	Normal	46.99	5.84	

Student's t-test. SD: Standard Deviation.

Discussion

Demographic data of participants: Males older than 50 years old made up more than half of the HCC patients who participated in current study. Comparatively, a Japanese study revealed similar results as men were more likely than women to get HCC, particularly among those who are older than 70 years (19). Also, Brunocilla et al. (2013) reported the same findings in their study as most of the participants were males with a median age of 67 years (20). These findings may be explained by the finding that compared to women, men are more likely to have viral hepatitis infections, drink more alcohol, smoke more cigarettes, and have a greater body mass index. Additionally, higher testosterone levels or the use of anabolic steroids have been linked to a higher incidence of HCC in males (21). The positive association between age and HCC incidence might be due to the effects of alcohol consumption on the development of HCC as it becomes significant with advancing age. This conclusion may be partially explained by the likely increased prevalence of alcoholic HCC in older patients in Korea (22). Moreover, regarding residency, those diagnosed in urban communities represented the majority of patients in current study. The same results were obtained in a study from the United States that included a percentage (75.8%) of patients with HCC receiving sorafenib who were diagnosed in an urban community (23). Quality of Life of Participants on Sorafenib Treatment Data from the current study revealed that the functional scales of EORTC QLQ-C30, emotional scale, and social scale were the most affected. Among the symptoms scales, fatigue and appetite loss scales were the most affected scales. However, patients in the current study had a better quality of life than those in an earlier study which involved 111 hospitals and cancer centers in 17 different countries using the EORTC QLQ-C30, with the exception of pain, diarrhea, appetite loss, dyspnea, and nausea (24). Another study conducted in Brazil found a higher QoL across all EORTC QLQ-C30 domains with the exception of the pain and emotional domains (25). Moreover, a study carried out in 20 nations in the Asia-Pacific, North America, and European regions revealed a better QoL across

all EORTC QLQ-C30 domains with the exception of fatigue and diarrhea (26).

Association between participants' quality of life and their demographic data:The Current study stated that patients with younger age had good QoL regarding physical scale, role scale, fatigue and pain scale. In agreement with these findings, Waldmann et al. (2013) revealed that aging is linked to a decline in QoL across all functioning scales (27). However, a study conducted in the United States revealed that patients under the age of 75 had improved mental QoL (28). which was consistent with a another study conducted in the United States that revealed that younger patients had more unmet needs in the emotional and mental health domains (29). In terms of gender effect, the emotional scale of women was significantly higher. In contrast, Shomura et al. (2016) stated that female sex is associated with poor QoL in HCC patients regarding physical scale (19). One possible explanation for these findings maybe that female patients with HCC are more likely to experience stigma because HCC is frequently associated with alcoholism or drug use. Also, somatic symptoms have a more detrimental effect on women's than they do on men's QoL (29). On the other hand, current study showed that there was a non-significant association between participants' residency and their educational level, with the QLQ-C30 domains. In addition, in current study, employed patients had a significantly better QoL regarding dyspnea scale. To our knowledge, no previous studies had discussed the relationship between residency, education and employment with quality of life in HCC patients taking sorafenib. Association between participants' quality of life and their experience of adverse drug effects Symptom scales/items in the current study were associated with lower scores on the EORTC QLQ-C30. In addition, the QLQ-C30 summary score indicated that the adverse event of weight loss is associated with a better QoL. Indeed, a previous study showed that adverse effects related to anticancer drugs may impact the quality of life resulting in interruption of treatment or reduction of drug dose, and thus decrease medication's optimal efficacy. This is particularly true when using sorafenib to treat advanced HCC (30). Also, Brose et al. (2014) concluded that the most frequent side effects of sorafenib therapy that could affect QoL include hand-foot skin reaction, gastrointestinal distress, and fatigue. Moreover, patients may be able to tolerate the full sorafenib dose with successful management of side effects. Overall, the key to preventing and managing side effects is patient empowerment and education, both before and during sorafenib treatment so that better QoL may be experienced by patients (31). However, the controversy may be linked to the patient's medical state, the severity of the adverse effects, and/or other influencing factors.

Ethical Clearance: Ethical Approval was obtained from the Scientific Research Ethics Committee and

Impact of sociodemographic characteristics and drug-related side effects   *Tuqa H. Qasim*
on quality of life of patients with hepatocellular carcinoma receiving sorafenib
treatment in Iraqi hospitals

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References:
1- *Myers, S., Neyroud-Caspar, I., Spahr, L., Gkouvatsos, K., Fournier, E., Giostra, E., Magini, G., Frossard, J.L., Bascaron, M.E., Vernaz, N. and Zampaglione, L. (2021). NAFLD and MAFLD as emerging causes of HCC: A populational study. JHEP Reports, 3(2),100231.*

2- *Bertuccio, P., Turati, F., Carioli, G., Rodriguez, T., La Vecchia, C., Malvezzi, M. and Negri, E. (2017). Global trends and predictions in hepatocellular carcinoma mortality. Journal of hepatology, 67(2), 302-309.*

3- *Fan, S.Y. (2011). Health-Related Quality of Life and Adjustment in Patients with Hepatocellular Carcinoma (Doctoral dissertation, University of Sheffield).*

4- *Farazi, P.A. and DePinho, R.A. (2006). Hepatocellular carcinoma pathogenesis: from genes to environment. Nature Reviews Cancer, 6(9), 674-687.*

5- *Cahill, B.A. and Braccia, D. (2004). Current treatment for hepatocellular carcinoma. Clinical journal of oncology nursing, 8(4), 393-400.*

6- *Waziry, R. (2018). Clinical epidemiology of hepatocellular carcinoma among people with hepatitis B or hepatitis C infection (Doctoral dissertation, UNSW Sydney).*

7- *Llovet, J.M., Ricci, S., Mazzaferro, V., Hilgard, P., Gane, E., Blanc, J.F., De Oliveira, A.C., Santoro, A., Raoul, J.L., Forner, A. and Schwartz, M. (2008). Sorafenib in advanced hepatocellular carcinoma. New England journal of medicine, 359(4), 378-390.*

8- *Daher, S., Massarwa, M., Benson, A.A. and Khoury, T.)2018(. Current and future treatment of hepatocellular carcinoma: an updated comprehensive review. Journal of clinical and translational hepatology, 6(1), 69.*

9- *Abdelgalil, A.A., Alkahtani, H.M. and Al-Jenoobi, F.I. (2019). Sorafenib. Profiles of Drug Substances, Excipients and Related Methodology, 44, 239-266.*

10- *Blanchet, B., Billemont, B., Barete, S., Garrigue, H., Cabanes, L., Coriat, R., Francès, C., Knebelmann, B. and Goldwasser, F. (2010). Toxicity of sorafenib: clinical and molecular aspects. Expert opinion on drug safety, 9(2), 275-287.*

11- *Heydarnejad, M.S., Hassanpour, D.A. and Solati, D.K. (2011). Factors affecting quality of life in cancer patients undergoing chemotherapy. African health sciences, 11(2), 266–270.*

12- *Lopez, J.H., Mayordomo, A.R., Rosado, R.L., Fernandez, C.I.S. and Gallana, S. (2009). Quality of life in long-term oral cancer survivors: a comparison*

with Spanish general population norms. Journal of oral and maxillofacial surgery, 67(8), 1607-1614.

13- *Ravasco, P. (2019). Nutrition in cancer patients. Journal of clinical medicine, 8(8), 1211.*

14- *Nagy, J. (2012). Quality of life of head and neck cancer patients after tumor treatment and subsequent maxillofacial rehabilitation (Doctoral dissertation, szte).*

15- *Luckett, T., King, M.T., Butow, P.N., Oguchi, M., Rankin, N., Price, M.A., Hackl, N.A. and Heading, G. (2011). Choosing between the EORTC QLQ-C30 and FACT-G for measuring health-related quality of life in cancer clinical research: issues, evidence and recommendations. Annals of Oncology, 22(10), 2179-2190.*

16- *Efficace, F., Cottone, F., Sommer, K., Kieffer, J., Aaronson, N., Fayers, P., Groenvold, M., Caocci, G., Coco, F.L., Gaidano, G. and Niscola, P. (2019). Validation of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 summary score in patients with hematologic malignancies. Value in Health, 22(11), 1303-1310.*

17- *Giesinger, J. M., Loth, F. L. C., Aaronson, N. K., Arraras, J. I., Caocci, G., Efficace, F., Groenvold, M., van Leeuwen, M., Petersen, M. A., Ramage, J., Tomaszewski, K. A., Young, T., & Holzner, B. (2020). Thresholds for clinical importance were established to improve interpretation of the EORTC QLQ-C30 in clinical practice and research. Journal of Clinical Epidemiology, 118, 1-8.*

18- *Husson, O., de Rooij, B. H., Kieffer, J., Oerlemans, S., Mols, F., Aaronson, N. K., van der Graaf, W. T. A., & van de Poll-Franse, L. V. (2019). The EORTC QLQ-C30 Summary Score as Prognostic Factor for Survival of Patients with Cancer in the "Real-World": Results from the Population-Based PROFILES Registry. The Oncologist, 25(4), e722-e732.*

19- *Shomura, M., Kagawa, T., Okabe, H., Shiraishi, K., Hirose, S., Arase, Y., Tsuruya, K., Takahira, S. and Mine, T., 2016. Longitudinal alterations in health-related quality of life and its impact on the clinical course of patients with advanced hepatocellular carcinoma receiving sorafenib treatment. BMC cancer, 16(1), 1-9.*

20- *Brunocilla, P.R., Brunello, F., Carucci, P., Gaia, S., Rolle, E., Cantamessa, A., Castiglione, A., Ciccone, G. and Rizzetto, M. (2013). Sorafenib in hepatocellular carcinoma: prospective study on adverse events, quality of life, and related feasibility under daily conditions. Medical Oncology, 30(1), 1-8.*

21- *Balogh, J., Victor III, D., Asham, E.H., Burroughs, S.G., Boktour, M., Saharia, A., Li, X., Ghobrial, R.M. and Monsour Jr, H.P. (2016). Hepatocellular carcinoma: a review. Journal of hepatocellular carcinoma, 3, 41.*

22- *Yi, S.W., Choi, J.S., Yi, J.J., Lee, Y.H. and Han, K.J. (2018). Risk factors for hepatocellular carcinoma by age, sex, and liver disorder status: a*

Impact of sociodemographic characteristics and drug-related side effects
on quality of life of patients with hepatocellular carcinoma receiving sorafenib
treatment in Iraqi hospitals

Tuqa H. Qasim

prospective cohort study in Korea. Cancer, 124(13), 2748-2757.

23- *Zhou, K., Pickering, T.A., Gainey, C.S., Cockburn, M., Stern, M.C., Liu, L., Unger, J.B., El-Khoueiry, A.B. and Terrault, N.A. (2021). Presentation, management, and outcomes across the rural-urban continuum for hepatocellular carcinoma. JNCI cancer spectrum, 5(1), pkaa100.*

24- *Galle, P.R., Finn, R.S., Qin, S., Ikeda, M., Zhu, A.X., Kim, T.Y., Kudo, M., Breder, V., Merle, P., Kaseb, A. and Li, D. (2021). Patient-reported outcomes with atezolizumab plus bevacizumab versus sorafenib in patients with unresectable hepatocellular carcinoma (IMbrave150): an open-label, randomized, phase 3 trial. The Lancet Oncology, 22(7), 991-1001.*

25- *Baldan Ferrari, G., Coelho França Quintanilha, J., Berlofa Visacri, M., Oliveira Vaz, C., Cursino, M.A., Sampaio Amaral, L., Bastos, B., Pereira, T.T., de Oliveira, G., Paulo, J. and de Godoy Torso, N. (2020). Outcomes in hepatocellular carcinoma patients undergoing sorafenib treatment: toxicities, cellular oxidative stress, treatment adherence, and quality of life. Anti-Cancer Drugs, 31(5), 523-527.*

26- *Vogel, A., Qin, S., Kudo, M., Su, Y., Hudgens, S., Yamashita, T., Yoon, J.H., Fartoux, L., Simon, K., López, C. and Sung, M. (2021). Lenvatinib versus sorafenib for first-line treatment of unresectable hepatocellular carcinoma: patient-reported*

outcomes from a randomized, open-label, non-inferiority, phase 3 trial. The Lancet Gastroenterology & Hepatology, 6(8), 649-658.

27- *Waldmann, A., Schubert, D. and Katalinic, A. (2013). Normative data of the EORTC QLQ-C30 for the German population: a population-based survey. PloS one, 8(9), e74149.*

28- *Deng, Y., Zhu, J., Liu, Z., Huang, M., Chang, D.W. and Gu, J. (2020). Elevated systemic inflammatory responses, factors associated with physical and mental quality of life, and prognosis of hepatocellular carcinoma. Aging (Albany NY), 12(5), 4357.*

29- *Burg, M.A., Adorno, G., Lopez, E.D., Loerzel, V., Stein, K., Wallace, C. and Sharma, D.K.B. (2015). Current unmet needs of cancer survivors: Analysis of open-ended responses to the American Cancer Society Study of Cancer Survivors II. Cancer, 121(4), 623-630.*

30- *Zhou, K. and Fountzilas, C. (2019). Outcomes and quality of life of systemic therapy in advanced hepatocellular carcinoma. Cancers, 11(6), 861.*

31- *Brose, M.S., Frenette, C.T., Keefe, S.M. and Stein, S.M. (2014). Management of sorafenib-related adverse events: a clinician's perspective. Seminars in Oncology, 41, S1-S16.*

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تاثير الخصائص الديموغرافية الاجتماعية والتاثيرات الجانبية للدواء على نوعية وجودة الحياة لمرضى سرطان الخلايا الكبدية الذين يخضعون لعلاج سورافينيب في المستشفيات العراقية

الصيدلانية تقى هيثم قاسم   طالبة ماجستير/فرع الفارماكولوجي/كلية الطب/جامعة بغداد

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الخلاصة:

الخلفية: سورافينيب هو مثبط متعدد للكيناز عن طريق الفم تم منحه الموافقة من قبل إدارة الغذاء والدواء الأمريكية لعلاج المرضى الذين تم تشخيص إصابتهم بسرطان الخلايا الكبدية وسرطان الخلايا الكلوية المتقدم. ومع ذلك، قد يوفر قياس جودة الحياة وملامح السمية أثناء علاج السرطان الأعراض التي أبلغ عنها المريض مزيدًا من المعلومات لتقييم ومقارنة فعالية العلاج وملامح السمية أثناء علاج السرطان. على الرغم من الأهمية الحاسمة لنوعية حياة المرضى أثناء تلقي العلاج المضاد للسرطان، لم يكن لدى المرضى العراقيين الذين يخضعون للأدوية المضادة للسرطان بشكل عام ولا أولئك الذين يتلقون سورافينيب على وجه الخصوص أي بيانات منشورة لتقييم هذا المعيار المهم.

هدف الدراسة: هو تقييم هذا المعيار المهم جودة حياة المرضى العراقيين الذين عولجوا من قبل سورافينيب والذين تم تشخيصهم بسرطان الخلايا الكبدية.

طريقة البحث: تم إجراء دراسة مستقبلية مقطعية مفتوحة التسمية في عيادة الأورام (مستشفى الأورام التعليمي، مستشفى الأمل، مدينة الإمامين الكاظمين الطبية في بغداد، العراق) خلال الفترة من تشرين الثاني 2021 إلى تموز 2022. تم اعتماد طريقة مناسبة لأخذ العينات لتسجيل المرضى في الدراسة الحالية. تم تقييم جودة الحياة باستخدام استبيان QLQ-C30 من المنظمة الأوروبية لأبحاث وعلاج السرطان. أجريت التحليلات الإحصائية باستخدام الحزمة الإحصائية للعلوم الاجتماعية (SPSS، الإصدار 20.0). لاختبار الاختلافات بين مجموعات الدراسة، تم استخدام (Student's t-test) و (ANOVA). تم استخدام اختبار (Chi-squared) لمقارنة نسبتين للبيانات الفئوية. اعتبرت قيمة P >0.05 ذات دلالة إحصائية.النتائج: تم تسجيل ما مجموعه 52 مريضا في الدراسة الحالية. كان الإرهاق هو الحدث الضار الأكثر شيوعًا حيث ظهر في 90.4٪ من المشاركين، يليه فقدان الشهية وفقر الدم والغثيان والإسهال (71.2٪، 67.3٪، 65.4٪، 59.6٪ على التوالي)، بينما أصيب 26.9٪ فقط من المشاركين بالتقيؤ. بالإضافة إلى ذلك، تم اكتشاف أن بعض المشاركين يتمتعون بنوعية حياة جيدة، إلا أن البعض الآخر لم يكن كذلك.

الخلاصة: المرضى الذين يعانون من سرطان الخلايا الكبدية في علاج سورافينيب يظهرون نوعية حياتهم المتغيرة. يتأثر هذا الأخير بشكل كبير بالخصائص الاجتماعية والديموغرافية للمرضى والآثار الضارة المرتبطة بالعقاقير.

الكلمات المفتاحية: سرطان الخلايا الكبدية، مثبط متعدد الكاينيز، نوعية الحياة، الاجتماعية الديموغرافية، سورافينيب.